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Remarks

Status of Claims

Claims 1-13 and 16-20 were rejected. Claim 16 and Claim 17 are amended. Claims 1-13, 16-22 remain pending.

The Claim amendments are supported by the application as filed. No new matter is added.

Claim Objection:

Claim 17 is amended to correct the typographical error pointed out by the Examiner. Withdrawal of the objection is requested.

§103 Rejections

Claims 1-13 are rejected as obvious over Burbank (5,526,822) in view of Banik (6053877) and further in view of Bryan (6488636). Applicant respectfully urges this rejection is improper for at least the following reasons.

The Office acknowledges that Burbank does not teach a sample tube releasably supported as recited in Claim 1. The Office also agrees that Burbank does not teach a cutter having a plurality of holes spaced from the distal end of the cutter. It is respectfully urged one would not be motivated to modify Burbank by the teachings of Banik or Bryan to obtain the subject matter of Claim 1.

First, the Examiner is requested to consider that Banik teaches a sample tube 20 and an outer sleeve 24 which move together to open and close jaws 14 (see column 4, lines 52-65).

"The sample tube 20 and outer sleeve 24 move together to open and close the jaws 14, 14' by applying camming forces to the jaws that plastically deform the hinges 36, 36' ")

Accordingly, Banik teaches the sample tube moves with the outer sleeve 24. One reading Burbank and Banik would not be motivated to provide a device having a hollow cutter advanceable within a biopsy needle and a sample tube advanceable within the hollow cutter, as recited in Claim 1. Instead, Banik teaches a sample tube should move with an outer portion of the biopsy device.

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Second, it is respectfully urged that there is not a reasonable expectation of success in making the combination suggested by the Examiner. The Examiner's position is that Banik teaches the sample tube is removed without disassembling the device, based on a reference to col 10, lines 3-17 of Banik. However, the Examiner is respectfully requested to reconsider the teachings of Banik. The portion of Banik relied on by the Examiner states:

"The sample tubes can be removed either by extending them distally through the open jaws or by an arrangement that permits the tubes to be withdrawn proximally while the rest of the device remains in the body. Such an arrangement would use a mechanical decoupling assemble to decouple the sample tube from the sheath and a geometry that allows bumps at the distal end of the tube to be withdrawn proximally through the entire length of the device."

Regarding Banik's suggestion to remove the tube distally through the open jaws, such an approach would not be workable in Burbank's device, since Burbank does not appear to have an end that can be opened by moving jaws, or otherwise open the distal end of Burbank's device.

Likewise, it is urged that Banik and Burbank taken together would not provide a sample tube removable from Burbank's proximal end. Banik mentions (but does not show) an "arrangement that permits the tubes to be withdrawn proximally", and also mentions (but does not show) "a mechanical decoupling assembly" that would allow the "bumps at the distal end of the tube to be withdrawn proximally through the entire length of the device."

The Examiner is respectfully requested to explain specifically how this hypothetical "arrangement" mentioned but not shown by Banik would teach or suggest one of ordinary skill in the art to modify Burbank as the Examiner suggests. In particular, since Banik's device is said to include "bumps" at the distal end of the sample tube, the Examiner is respectfully requested to specifically explain how such bumps on a sample tube could be withdrawn proximally through the cutter of Burbank.

It is respectfully urged that the Examiner has merely assumed that an arrangement mentioned but not described or shown in Banik would work in Burbank's device. A prima facie case of obviousness requires a reasonable expectation of success. The Examiner is respectfully urged to

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explain specifically how one would adapt the mechanical decoupling assembly of Banik to work in Burbank, so that Applicant has a full and fair opportunity to respond.

Third, Claim 1 recites, among other things, that the cutter has a plurality of holes spaced from the distal end of the cutter, wherein the plurality of holes are formed transversely through the sidewall of the cutter and positioned for providing vacuum axially through the cutter when multiple samples are disposed within the sample tube within the cutter. It is respectfully urged that neither Burbank, nor Banik, nor Bryan teach or suggest such a feature.

The Examiner cites Bryan as teaching holes 114 in a basket tube 18. Bryan also teaches a cutting tube 24. However, it is respectfully urged that Bryan does not teach or suggest that the cutting tube 24 has a plurality of holes spaced from a distal end of a cutter, or a plurality of holes formed transversely through the sidewall of a cutter, or such holes positioned for providing vacuum axially through a cutter when samples are disposed within a sample tube within the cutter.

So, even if one combines all three references, the resulting combination would not provide all the elements of Claim 1. Accordingly, the Examiner has not made out a prima facie case of obviousness, and the rejection should be withdrawn.

Claim 16-20 and 22:

Claim 16-20 and 22 is rejected as over Burbank in view of Banik. It is respectfully urged that one would not be motivated to combine Burbank's device with Banik's device, as suggested by the Examiner, for at least the reasons set forth above.

Additionally, even if one combined Burbank and Banik as suggested by the Examiner, the resulting combination would not provide the subject matter of Claim 16. For instance, as explained above, the two references, even if combined, do not teach or suggest a hollow cutter having an open distal end, a lumen extending proximally from the open distal end, and a plurality of holes spaced from the distal end and extending through a wall of the cutter.

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Claim 17:

The Examiner rejection of Claim 17 is improper for at least the following reasons.

First, the Examiner states that Banik discloses a hollow sample tube 20 advanced in a "hollow cutter 14." This is not correct.

Banik actually teaches that element 14 is one of two jaws 14,14', not a hollow cutter. Accordingly, the Examiner cannot fairly characterize Banik as teaching or suggesting a hollow cutter, or advancing a sample tube in a hollow cutter.

Second, even if one combined Banik and Burbank, and even if (for the sake of argument only), one considered the jaws 14,14' of Banik to be a hollow cutter, the rejection would still be improper. That is because combining the two references would not teach:

wherein at least a portion of the act of advancing the hollow sample tube is performed after the cutter has reached the distalmost position and after the cutter has encapsulated the severed tissue sample

Note that in Banik, even if the jaws 14,14' are considered a hollow cutter, this step is not taught or suggested. Instead, as the Examiner notes, Banik teaches at col. 6, lines 43-48 that:

*As the jaws close in radial motion, they urge tissue separated from the surface slightly proximally. At the same time, the sample tube 20 moves axially distally. The combined effects of the jaws and the tube tend to urge or stuff sample into the open end 21 of the sample tube 20. (italics added)*

Accordingly, it is clear that the act of advancing the sample tube 20 of Banik is not performed after the jaws 14,14' of Banik have reached a distalmost position. In addition, Banik teaches that the jaws close in radial motion, not by axial motion. Accordingly, the combination of Burbank and Banik would not teach all the method steps of Claim 17.

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Applicant further notes that the dependent claims include additional limitations not taught or suggested in the art of record, thus forming independent basis for non-obviousness.

Conclusion

While several distinctions have been noted over the art of record, Applicant notes that there are several other limitations recited in the present claims that are neither taught nor suggested by the art of record. Applicant expressly reserves all rights and arguments, including those made in previous responses, with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance.

Respectfully submitted,

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